

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
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Date of mailing
(day/month/year) **11 JUL 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION
See paragraph 2 below

58768.000006

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/07201

07 March 2005 (07.03.2005)

05 March 2004 (05.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 51/00 and US Cl.: 424/1.29, 1.25; 600/7

Applicant

XL SCI-TECH, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/07201

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/07201

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>19 and 20</u>	YES
	Claims <u>1-18 and 21-35</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-35</u>	NO
Industrial applicability (IA)	Claims <u>1-35</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-18 and 21-35 lack novelty under PCT Article 33(2) as being anticipated by DAY (US 4,789,501). DAY discloses an implant for radiotherapy comprising a resorbable glass matrix and a radioactive isotope, as claimed, see columns 2-3. The glass matrix comprises phosphate materials with alumina, etc., in amounts encompassed by the claims, see column 5. The radioactive isotope includes Y-90, etc., see column 6. While the invention of DAY includes the use of stable isotopes and irradiation, this is only one aspect of the DAY, but is not required. DAY also discloses methods of making the implants that do not use irradiation, see columns 2 and 8-9.

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over DAY (US 4,789,501) in view of CONIGLIONE (US 6,589,502). DAY discloses an implant for radiotherapy comprising a resorbable glass matrix and a radioactive isotope, as set forth above. DAY fails to specifically disclose the use of a biopolymer delivery vehicle as claimed. CONIGLIONE discloses implants for radiotherapy and teaches that various biopolymers (as claimed) provide the advantages of enabling the implants to be formed in a desired size and shape and providing a predetermined rate of biodegradation, see abstract and Table I, column 22. It would have been obvious to one of ordinary skill in the art to use a biopolymer delivery vehicle for the implants of DAY to provide the advantages taught thereby in the art by CONIGLIONE.

Claims 19 and 20 meet the criteria set out in PCT Article 33(3), because the prior art does not teach the implants as claimed having a glass matrix and a biopolymer delivery vehicle.

Claims 1-35 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.